Remarks

The claims required to be corrected by the Notice of Non-Compliant Amendment have been corrected. Note that claim 4 had an error other than the identified error, which has been corrected by re-doing the underlining using a redlining program to make the changes clearer. The remainder of the remarks from Amendment A as originally submitted are being resubmitted here, without change.

The applicant will address all the points raised by the Examiner and demonstrate that claims 1-33 are patentable for the reasons provided below.

35 U.S.C. § 112, ¶ 2 (Definiteness)

The applicant has been requested to provide an antecedent basis in claim 1 for "said pump" in claim 2. The requested antecedent basis has been added in claim 1, part E. This amendment is believed to overcome the basis for this rejection.

35 U.S.C. § 102 (Novelty) - Alford, et al.

The applicant has been asked to show that claims 1-3, 10, 21-25, and 30-32 in this case are novel compared to the Alford, et al. references (WO03/024214, US 2003/0054540, and 6,677,150) (here relying on WO 03/024214 for page and line citations – all three references are believed to be subject to the same arguments). The applicant respectfully submits that these claims are novel because the present claims and the Alford, et al. prior art differ.

Claim 1, and thus all the others (which depend from claim 1), is distinguished from the Alford, et al. references because that claim recites, "the organ container, the bubble remover, the oxygenator, and the perfusion loop are movable into and out of the outer container and into and out of an operative relationship with the pump while the perfusion loop remains closed," which the Alford, et al. references do not teach.

Alford, et al. does not disclose a perfusion fluid loop that can be moved into or out of operative contact with the pump (operative contact is contact allowing fluid to be pumped in the perfusion fluid loop) while the perfusion loop remains closed. For example, in Alford, et al. there is

no disclosure of removing a subassembly including the entire perfusion loop as a unit without opening the loop. In fact, the connections at the pump 4 in Figure 4 must be broken at or near 5, opening the perfusion loop, to remove the perfusion loop. Alford, et al. therefore does not achieve a benefit of claim 1, which is that the perfusion loop assembly can be provided in a sterile package, loaded with an organ and perfusion fluid, closed in a sterile field, then moved into operative contact with the pump and chiller while the perfusion fluid loop remains closed. The mechanical and electrical components of the organ transporter, which may include the oxygen bottle, the chiller, the pump, the battery, and so forth, thus can be used without sterilizing them, reserving sterile components and technique for the perfusion loop. This arrangement also has the advantage that the perfusion loop assembly can all be disposable and have few moving parts.

Claims 1-3, 10, 21-25, and 30-32 are therefore novel.

35 U.S.C. § 102 (Novelty) - Owen et al.

The applicant has been asked to show that claims 1-3 and 5-32 in this case are novel compared to the Owen et al. reference. The applicant respectfully submits that these claims are novel because those claims (claim 1 and its dependent claims) all require that "the organ container, the bubble remover, the oxygenator, and the perfusion loop are movable into and out of the outer container and into and out of an operative relationship with the pump while the perfusion loop remains closed." The Owen et al. reference does not teach or suggest this feature. For example, the tubing 50c of Owen et al. conducts perfusion fluid to the organ (see Figs. 1 and 2). Fig. 1 of Owen et al. shows the upper end of the tubing 50c passing through a small hole in the cabinet, and the tubing is connected to larger structure at each end. The tubing 50c physically cannot be removed from the cabinet without breaking a connection in the path of perfusion fluid.

Claims 1-3 and 5-32 are therefore novel.

35 U.S.C. § 103 (Non-obviousness) – Alford, et al. v. Olympus

The applicant has been asked to show that claims 3-9 in this case are non-obvious in view of the Alford, et al. references discussed above, in view of Olympus. The applicant respectfully submits that these claims are non-obvious, for the reasons provided below. The applicant is relying

on the Figures and the English language abstract of the Olympus reference obtainable on ESPACENET.com, not on its Japanese language text, in the following discussion.

Claims 3-9 each recite, by virtue of dependency from claim 1, "the organ container, the bubble remover, the oxygenator, and the perfusion loop are movable into and out of the outer container and into and out of an operative relationship with the pump while the perfusion loop remains closed." The Olympus reference does not disclose this feature. For example, there is no indication that the perfusion loop and its components in Olympus can be disengaged from the pump 7 without opening the perfusion loop. The rejected claims are therefore novel, notwithstanding the Olympus reference.

As mentioned above, the Alford, et al. references do not disclose apparatus in which "the organ container, the bubble remover, the oxygenator, and the perfusion loop are movable into and out of the outer container and into and out of an operative relationship with the pump while the perfusion loop remains closed." Therefore, neither applied reference discloses this element.

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. * * *. [T]he prior art reference (or references when combined) must teach or suggest all the claim limitations."

§ 2142 MANUAL OF PATENT EXAMINING PROCEDURE, 8th ed., Rev. 5. Neither applied reference discloses a perfusion loop assembly that can be removed without opening the loop.

Additionally, there is no apparent basis for concluding, with respect to present claims 6, 8, and 9, that the Olympus device is configured to heat the perfusion fluid or provide a particular time-temperature profile.

Claims 3-9 are therefore non-obvious in view of the cited prior art.

35 U.S.C. § 103 (Non-obviousness) – Alford, et al. v. Owen et al.

The applicant has been asked to show that claims 11-20 and 26-29 are not obvious in view of a combination of the Alford, et al. and Owen et al. references. These claims depend from claim 1. As shown above, neither Alford, et al. nor Owen et al. discloses a feature required in claim 1: "the organ container, the bubble remover, the oxygenator, and the perfusion loop are movable into and out of the outer container and into and out of an operative relationship with the pump while the

perfusion loop remains closed." Due to these missing elements, claims 11-20 and 26-29 are not obvious in view of a combination of the Alford, et al. and Owen et al. references.

35 U.S.C. § 103 (Non-obviousness) –Owen et al.

The applicant has been asked to show that claim 4 is not obvious in view of Owen et al. As shown above, Owen et al. does not render claim 1 obvious, and claim 4 depends from claim 1. Therefore, claim 4 is not obvious in view of the Owen et al. reference.

Obviousness Type Double Patenting

The judicially created rule against obviousness-type double patenting has been cited respecting numerous claims of this application and various claims of U.S. Patent No. 6,677,150 ("the Alford, et al. US patent"). The rule only requires that a claim which is obvious in light of subject matter claimed in a prior issued, commonly-owned patent must expire on the same date as the prior patent.

> [T]he first question [in a double patenting analysis] is: Is the same invention being claimed twice[?] If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting. * * * If the rejected claim defines more than an obvious variation, it is patentably distinct."[1]

All of the present claims are patentably distinct, compared to the cited claims of the Alford, et al. US patent. This is so at least for essentially the same reasons provided above in response to the rejections under 35 USC 102 and 103, as the claims in the Alford, et al. US patent do not recite features required in all the present claims: "the organ container, the bubble remover, the oxygenator, and the perfusion loop are movable into and out of the outer container and into and out of an operative relationship with the pump while the perfusion loop remains closed."

Therefore, these claims should be allowed and the double patenting issues withdrawn.

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[1] General Foods Corporation v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 23 U.S.P.Q.2d 1839 (Fed. Cir. 1992) (emphasis in original).

35 U.S.C. § 102(g) - Alford, et al.

The applicant has been requested to show why the present claims do not raise a priority (102(g)) or derivation (102(f)) issue between the present application and the Alford, et al. US patent. Neither issue arises in this instance, so the issues should be withdrawn.

There should be no priority issue because, as explained above, the present claims and those of the Alford, et al. US patent do not claim obvious variations of the same invention.

There should be no derivation issue because the present claims are not obvious in view of the disclosure of the Alford, et al. US patent.

35 U.S.C. § 132 (Amendments Supported)

The amendment to claim 1 reciting "portable" apparatus is supported in paragraph [0132], which states as follows: "It will thus be seen that we have provided a portable organ transport device that will maintain the viability of an organ for 24 hours or more."

The amendment to claim 1 reciting "an organ container comprising an interior space" is supported in Figure 4 which shows an organ container having an interior space (see reference character 8), as well as in Figures 8 and 10.

The amendment to claim 1 reciting "a bubble remover comprising a headspace and a venting valve" is supported by:

- paragraph [0109], which states as follows: "For example, a detector can be placed near the valve 13 in the adjacent headspace .... The processor can be programmed to vent the headspace whenever excess gas requiring venting is present, or it can be programmed to keep the valve closed if there is insufficient gas in the headspace or no gas requiring venting;"
- paragraph [0065], which states as follows: "The cover 11a of the chamber 11 can be equipped with a one-way venting valve 12 through which gases can be vented to the atmosphere;" and
- Figure 1.

The amendment to claim 1 reciting "an oxygenator comprising a chamber for receiving perfusion fluid, a gas space for receiving oxygen, and a gas exchange interface allowing gas exchange between the chamber and the gas space" is supported in paragraphs [0063]-[0064], which state as follows: "The oxygenator 21 can be in the form of a hollow chamber .... A quick connect oxygen inlet fitting 5a communicates with the interior of the oygenator 21 by (for example) 4-6 gas permeable Silastic® polymer tubes 22 through which oxygen can be transferred to the perfusion fluid in the oxygenator 21. * * * While an exemplary device uses Silastic® tubing for gas exchange, it should be understood that other silicone tubing or other materials may be used. * * * Thin polyethylene sheets can be used to make a functioning oxygenator in an assembly like an automobile radiator. Such an assembly could, for example, be housed inside a tube which is connected in line with the perfusion fluid path." The interior of the described tubing or "assembly like an automobile radiator" describes the recited "gas space".

The amendment to claim 1 reciting "D. a perfusion loop comprising the organ container interior space, the bubble remover headspace, and the oxygenator chamber interconnected to provide fluid circulation," is supported in:

- paragraph [0085], which states as follows: "As shown schematically in Figure 9, the organ transporter can be provided in the form of a disposable portion 119 and a reusable portion shown in the remainder of the Figure. The disposable portion 119 can include, for example, the perfusion loop components ...;"
- paragraph [0087], which states, "The adapter 7, organ container 8, bubble remover 11, oxygenator 21, associated tubing, and a supply of perfusion fluid can be sterilized and provided in the operating room where the organ is harvested, attached to the adapter 7, placed within the organ container 8, and connected by suitable lengths of color-coded disposable sterile tubing to the bubble remover 11, oxygenator 21, and oxygen bottle 17. This assembly is disposable after a single use and forms a closed system isolated from ambient conditions and contaminants;" and
- Figure 9 which shows the illustrated parts (see reference characters 8, 11, 21 and 125 and associated tubing).

The amendment to claim 3 reciting "in which the perfusion loop further comprises a heat exchange surface" is supported in paragraph [0098], which states as follows: "The organ container or a separate fluid reservoir can include a high surface-area heat transfer surface, such as a heat-conductive wall or bottom. This heat transfer surface can be part of the unit that is disposable after a single use. This container can be placed in with its heat-conductive bottom or other wall in close thermal conductive contact with a heat-conductive outer surface of a Peltier-effect heat pump," and in Figure 9 which shows the claimed structure (see reference character 124).

The amendment to claim 1 reciting "E. a pump configured for circulating a perfusion fluid through the perfusion loop" is supported in paragraph [0067], which states as follows: "The pump assembly 24 comprises ... a DC brush motor 32 and an AC transformer and AC/DC converter 33 to supply 12-volt DC to the motor when AC current is available," and in Figure 9 which shows the pump 24 pumping fluid through the perfusion loop.

The amendment to claim 4 reciting, "further comprising a chiller configured for operative association with the heat exchange surface to cool a perfusion fluid circulating in the perfusion loop," and the amendment to claim 5 reciting, "The apparatus of claim 3 in which the chiller is a Peltier-effect thermoelectric heat pump," are supported in paragraphs [0096]-[0097], which state as follows: "The arrangement of Figure 9 further includes a Peltier-effect heat pump 123 thermally linked, as by a common, heat conductive wall 124, to a reservoir 125. * * * Such a chiller does not require a fluid refrigerant or heat sink.... * * * [T]he Peltier-effect heat pump consumes electricity to pump heat...."

The amendment to claim 1 reciting "F. an outer container sized and configured to contain the organ container, the bubble remover, the oxygenator, the perfusion loop, the pump, and a supply of oxygen in an operative relationship," is supported in paragraphs [0085]-[0087], which state as follows: "As shown schematically in Figure 9, the organ transporter can be provided in the form of a disposable portion 119 and a reusable portion shown in the remainder of the Figure. The disposable portion 119 can include, for example, the perfusion loop components.... The reusable part can include, for example, the outer container, oxygen bottle, battery, chiller, electronics and pump (except for the tubing defining the perfusion path, in certain embodiments). * * * The

adapter 7, organ container 8, bubble remover 11, oxygenator 21, associated tubing, and a supply of perfusion fluid can be sterilized and provided in the operating room where the organ is harvested, attached to the adapter 7, placed within the organ container 8, and connected by suitable lengths of color-coded disposable sterile tubing to the bubble remover 11, oxygenator 21, and oxygen bottle 17." See also Figures 2-6.

The amendment to claim 1 reciting "the organ container, the bubble remover, the oxygenator, and the perfusion loop are movable into and out of the outer container and into and out of an operative relationship with the electrically powered pump while the perfusion loop remains closed" is supported in paragraph [0085], which states as follows: "As shown schematically in Figure 9, the organ transporter can be provided in the form of a disposable portion 119 and a reusable portion shown in the remainder of the Figure. The disposable portion 119 can include, for example, the perfusion loop component." See also paragraph [0088], which states, "This assembly is disposable after a single use and forms a closed system isolated from ambient conditions and contaminants. The closed system can then be removed from the sterile field and assembled with the reusable components of the organ transporter. [T]he organ container 8 can be placed in heat exchange relation to the chiller, and the disposable components can be secured in the outer container to prepare for transport. The process can be reversed at the destination to unload the organ."

New claim 33 reciting, "the organ container, bubble remover, and oxygenator are mechanically joined, enabling them to move as a unit," is supported in Figure 5, which shows the organ container 8, bubble remover 11, and oxygenator 14 as a mechanically joined assembly, and paragraph [0098], which states as follows: "The organ container or a separate fluid reservoir can include a high surface-area heat transfer surface, such as a heat-conductive wall or bottom. This heat transfer surface can be part of the unit that is disposable after a single use."

New claim 34 recites "a support on which the perfusion loop and its components are carried together." This limitation is supported by paragraph [0085], which states in relevant part,

> As shown schematically in Figure 9, the organ transporter can be provided in the form of a disposable portion 119 and a reusable portion shown in the remainder of

the Figure. The disposable portion 119 can include, for example, the perfusion loop components and optionally a tray to support them when they are separated from the reusable part.

New claim 35 claims a coolant vessel configured to contain a coolant cooled by the chiller, wherein said heat exchange surface is disposed within the coolant vessel for contacting a coolant in the vessel. This limitation is supported by paragraphs [0079]-[0081], which state in relevant parts:

[0079] Alternative cooler arrangements are shown in Figs. 7-9.... Referring first to Figure 7, the cooler arrangement 101 of this embodiment comprises a 10-liter container 103 ... containing about 8 liters of a fluid cooling medium 105 and a cooling coil 107.

[0080] * * * The coil 107 has an inlet 109 and an outlet 111 projecting through the wall of the container 103 and a central or bight heat transfer portion 113 immersed in the fluid cooling medium 105. * * *

[0081] The coil 107 ... can be heat-conductive. * * * The inlet and outlet 109 and 111 of the cooling coil can be connected by biocompatible flexible tubing to the perfusion fluid circuit, for example by connecting the inlet 109 to the outlet of the bubble remover 11 and the outlet 111 to the adapter 7 as shown in Figure 1.

The amendments in this paper are therefore free of new matter.

Conclusion

The applicant has shown that this application satisfies all the legal requirements pointed out by the Examiner. Therefore, the Examiner is respectfully requested to prepare a Notice of Allowability allowing all the pending claims (1-33).

Please charge any fees required in connection with this filing or credit any overpayment of fees to McAndrews, Held & Malloy Deposit Account No. 13-0017.

Respectfully submitted,

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